

TARTER KRINSKY & DROGIN

Counsel for NAS Children Ad Hoc Committee

1350 Broadway, 11th Floor

New York, NY 10018

Tel: (212) 216-8000

Scott S. Markowitz, Esq.

Rocco A. Cavaliere, Esq.

Michael Z. Brownstein, Esq.

Email: smarkowitz@tarterkrinsky.com

Email: rcavaliere@tarterkrinsky.com

Email: mbrownstein@tarterkrinsky.com

UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re:

PURDUE PHARMA L.P., *et al.*,

Debtors.¹

Chapter 11

Case No. 19-23649 (RDD)

(Jointly Administered)

NOTICE OF HEARING REGARDING CHALLENGE LETTER

PLEASE TAKE NOTICE, that in accordance with the terms of the Third Amended Protective Order (“**Protective Order**”) [Dkt. 1935], on December 9, 2021, the NAS Children Ad Hoc Committee (“**NASC**”), submitted a letter through the Creadore Law Firm, PC, requesting judicial relief ordering the downgrading to ‘public’ information that Debtors have designated as ‘confidential’ pursuant to the Protective Order (the “**Challenge Letter**”) and on December 14,

¹ The Debtors in these cases, along with the last four digits of each Debtor’s registration number in the applicable jurisdiction, are as follows: Purdue Pharma L.P. (7484), Purdue Pharma Inc. (7486), Purdue Transdermal Technologies L.P. (1868), Purdue Pharma Manufacturing L.P. (3821), Purdue Pharmaceuticals L.P. (0034), Imbrium Therapeutics L.P. (8810), Adlon Therapeutics L.P. (6745), Greenfield BioVentures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF L.P. (0495), SVC Pharma L.P. (5717) and SVC Pharma Inc. (4014). The Debtors shall include their affiliates and other entities under their control. The Debtors’ corporate headquarters is located at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

2021, Debtors submitted a letter response (**"Debtors' Response"**). See, respectively, Exhibits 'A' and 'B' hereto.

PLEASE TAKE FURTHER NOTICE that, at the court's direction, a hearing on the Challenge Letter (the **"Hearing"**) has been scheduled for **February 17, 2022, at 10:00 a.m. (Prevailing Eastern Time)** before the Honorable Robert D. Drain, United States Bankruptcy Judge, United States Bankruptcy Court for the Southern District of New York, 300 Quarropas Street, White Plains, New York, 10601 (the **"Bankruptcy Court"**); *provided*, that, pursuant to General Order M-543, dated March 20, 2020 (Morris, C.J.) (**"General Order M-543"**), such Hearing shall be conducted **via Zoom for Government®** so long as General Order M-543 is in effect or unless otherwise ordered by the Bankruptcy Court.

PLEASE TAKE FURTHER NOTICE that parties wishing to participate in the Hearing are required to register their appearance by **4:00 p.m. (Prevailing Eastern Time)" the day before the Hearing** at <https://ecf.nysb.uscourts.gov/cgi-bin/nysbAppearances.pl>.

PLEASE TAKE FURTHER NOTICE that the Hearing may be continued or adjourned thereafter from time to time without further notice other than an announcement of the rescheduled date or dates in open court at the Hearing.

Dated: January 27, 2022
New York, New York

TARTER KRINSKY & DROGIN LLP
Counsel for NAS Children Ad Hoc Committee

By: /s/ Scott S. Markowitz

Scott S. Markowitz, Esq.
Rocco A. Cavaliere, Esq.
Michael Z. Brownstein, Esq.
1350 Broadway, 11th Floor
New York, NY 10018

Tel: (212) 216-8000
Scott S. Markowitz, Esq.
Rocco A. Cavaliere, Esq.
Michael Z. Brownstein, Esq.
Email: smarkowitz@tarterkrinsky.com
Email: rcavaliere@tarterkrinsky.com
Email: mbrownstein@tarterkrinsky.com

MARTZELL, BICKFORD & CENTOLA

Scott R. Bickford (LA 1165)
Spencer R. Doody (LA 27795)
338 Lafayette Street
New Orleans, LA 70130
Telephone: 504-581-9065
Facsimile: 504-581-7635
sbickford@mbfirm.com
srd@mbfirm.com
usdcndoh@mbfirm.com

CREADORE LAW FIRM PC

450 Seventh Avenue, 14th Floor
New York, NY 10123
Telephone: 212.355.7200
Donald Creadore, Esq. (NY 2090702)
donald@creadorelawfirm.com

**LAW OFFICES OF KENT HARRISON
ROBBINS, P.A.**

242 Northeast 27th Street
Miami, Florida 33137
Telephone: (305) 532-0500
Facsimile: (305) 531-0150
Email: khr@khrlawoffices.com

CHALLENGE LETTER

EXHIBIT A

THE CREADORE LAW FIRM P.C.
450 SEVENTH AVENUE – SUITE 1408
NEW YORK, NEW YORK 10123
Tel. 212.355.7200
Fax. 212.583.0412

Admitted: NY, CT, MO

December 8, 2021

VIA EMAIL ONLY

Hon. Robert D. Drain
U.S. Bankruptcy Court for the Southern District of New York
300 Quarropas Street
White Plains, NY 10601

Re: In re Purdue Pharma L.P., et al. (“Purdue” or “Debtors”), No. 19-23649 (RDD)

Dear Judge Drain:

The NASAHC submits this Challenge Letter under the terms of the *Third Amended Protective Order* [Dkt. 1935] (the “Protective Order”) in support of de-designating certain discovery materials that the producing party—Debtors—have designated as ‘Confidential’ pursuant to the Protective Order. For the reasons discussed below, it is both proper and reasonable for the Court to grant the relief sought by this Letter Challenge, by downgrading one or more of the documents identified in schedule accompanying this Challenge Letter from its current status to ‘public’ (the “Documents”).

NECESSITY OF THE DOCUMENTS

All fetuses exposed to opioids share a common injury of fetal opioid exposure. While many babies are diagnosed with NAS (neonatal abstinence syndrome) at birth, or in the days following birth undergo NOWS (neonatal opioid withdrawal syndrome), or present symptoms and conditions associated with fetal opioid exposure, other babies are discharged with malformations and disorders as well as latent injuries that will only manifest during infancy and pre-school and beyond. Downgrading of the Documents can afford immediate relief to all children that suffer from fetal opioid exposure by, for instance, assisting them in assessing injuries and, also, enhancing their understanding of fetal opioid exposure and the need for treatment of children injured by fetal opioid exposure. The need to know is immediate, real and credible.

The existence of a variety of potential health impacts to fetuses exposed to opioids during pregnancy but not manifested at birth—latent injuries—is both medically and biologically consistent with two of the research studies sought to be downgraded to ‘public’; namely,

These research studies

██████████ Upon information and belief, neither of these research studies was ever disclosed to the FDA.

After reviewing tens of millions of pages, the NASAHC now seeks to downgrade twelve (12) scientific documents (see Schedule, 'Set 1') that, among other features, contain information that is relevant, material and beneficial to NAS Claimants in terms of, for instance, assessing injuries ██████████ and other long-term impacts. The findings and entries reported in these scientific documents are among the reference sources the NASAHC relied upon for establishing the list of medical conditions qualifying under the NAS PI-TDP, such as skull and other skeletal malformations, feeding complications, respiratory dysfunction, and behavioral issues. These medical conditions represent a portion of the greater universe of medical conditions that are commonly associated with fetal opioid exposure, notwithstanding the absence of a documented NAS diagnosis at birth or observable signs of NOWS following birth. Currently, these scientific documents are not available to the public; rather, they are only available for limited use by—as well as of limited value to—the relatively small set of individuals agreeing to be bound by the terms of the PO. Removing the veil of confidentiality will make the scientific documents accessible to all NAS Claimants, whether appearing pro se or through retained counsel, serving the interests of justice.

PROCEDURAL BACKGROUND:

This Challenge Letter arises from two, separate, Challenge Notices that the NASAHC served upon the Producing Party (i.e., the Debtors) under the terms of the Protective Order; see Exhibit A. The first challenge notice, dated November 18, 2021 (the "**November 18 Notice**"), seeks Debtors' consent to downgrading to 'public' certain documents, consisting of (a) various materials introduced as exhibits during the deposition of Dr. Richard Fanelli (the individual Debtors had designated as a 30b6 records custodian) [see, Dkt. No. 3399] (the "**Fanelli Deposition**") and, (b) the scientific documents that remain the subject of prior discovery requests and meet and confers. The second notice, dated November 22, 2021 (the "**November 22 Notice**"), is limited to a series of Purdue's CCDS (company core data sheet) and, especially, the subject matter regarding the topics of Pregnancy, the risks of NOWS, toxicology, and preclinical and clinical data (both animal and human). Purdue's maintenance of a library of numerous versions of its CCDS (see accompanying Schedule) has also been the topic of many communications and meet and confers.¹

On November 23, 2021, Debtors sent the NASAHC a "letter [that] constitutes the Debtors' written response to your challenge notices" (the "**Debtors' Response**") (Exhibit 'B', hereto); in the course of declining to provide consent Debtors presented the following three arguments:

- (1) "the issue of which documents to make public and when such documents will be made public is already firmly established under the Debtors' twelfth amended plan..."; while also observing that "now is not the appropriate time to undertake such a timely and costly review,....., the Plan explicitly addresses this very issue."

¹ In sum, Debtors have denied the significance, if not the existence, of the 'Central Repository, Stamford CT', ultimately dismissing it as a closed matter. In stark contrast, Dr. Fanelli testified that Purdue maintained a Central Repository in Stamford, CT, and explained it had been securely kept within the parking garage due to the heavy load. Fanelli Deposition 156:4-158:2.

- (2) Mootness. The Chapter 11 cases before the Court has resulted in the Court confirming Debtors' Plan and none of the documents subject to the Challenge Notice are part of the record of the appeal.
- (3) "Third, the documents subject to the Challenge Notice are correctly designated as either "Confidential Information" or "Highly Confidential Information" under the Protective Order." (internal quote marks in original)

Because of the NASAHC's inability to obtain the consent of the Producing Party, the NASAHC is delivering this Challenge Letter requesting court approval for downgrading the Documents to 'public' in accordance with the terms of the Protective Order.²

ARGUMENT:

Debtors' third argument—that the designations are proper in all respects under the Protective Order—fails to account for the fact that the Producing Party ultimately bears the burden to "explain in writing to such Receiving Party (here, the NASAHC) the basis for the chosen...designation." Inexplicably, Debtors' Response recites (in full) the definitions to "Confidential Information" and "Highly Confidential Information" at footnotes 3 and 4 (repeated below)³, while neglecting to tie—by way of explanation as the basis for a chosen designation—any of the enumerated grounds to enforce the current document designations, let alone continue enforcement of such designations.

Debtors' Response fails to substantiate the correctness of the document designations. For instance, without any specificity, citation, or reference to any particular document or group of documents Debtors' Response groundlessly asserts that "[t]he documents designated as Confidential contain personally identifying information and/or research and technical information that the Debtors have maintained as confidential." This form of explanation violates both the standards set in the Protective Order (at ¶ 65: explain the basis of the chosen designation) and Rule 26(c)'s good cause requirement. By design, the terms of the Protective Order are akin to a blanket protective order that temporarily postpones the good cause showing until a party or intervenor challenges the continued confidential treatment of certain documents. The burden of establishing good cause lies with the party seeking to prevent the disclosure of documents and, here, Debtors have not met their burden. In addition to failing to explain the

² Copies of emails exchanged by and between the parties, consisting of the Challenge Notices and the Debtors' Response, are attached as Exhibit A and B, respectively.

³ Under the Protective Order, "Confidential Information" (¶ 8) means any Discovery Materials designated as Confidential on the basis that it constitutes, reflects, discloses, or contains information that is or could be protected from disclosure by law as (i) personally identifying information, (ii) personal information relating to a Family Member, (iii) medical or psychiatric information, (iv) personnel records, (v) law enforcement materials, (vi) research, technical, commercial, financial, banking or investment information that the Producing Party has maintained as confidential, (vii) such other information which would be entitled to protection on a motion for a protective order pursuant to the Federal Rule of Civil Procedure 26(c), as incorporated by Federal Rule of Bankruptcy Procedure 7026.", and "Highly Confidential Information" (¶ 15) means any Discovery Material designated as Confidential that constitutes, reflects, discloses, or contains information that the Producing Party has maintained as confidential and (i) the disclosure of which would allow a Market Participant to gain a material advantage in the marketplace such that it qualifies as a trade secret under applicable law, or (ii) the disclosure of which would be likely to cause commercial harm to the Producing Party or to the business partners or counterparties of the Producing Party.

basis of the designation chosen, it is noteworthy that Debtors have not argued that these Documents constitute trade secrets⁴ or, similarly, that disclosure now would provide an unfair benefit to a competitor. Nor could they: if only for the obvious fact that many of the Documents are one or more decades old and, therefore, represent little if any commercial value at this time. In stark contrast, the Documents are of especial interest and value to the thousands of NAS Claimants participating in the claims administration process, and also of "especial public interest." Gelb v. Am. Tel. & Tel. Co., 813 F.Supp. 1022, 1036 (S.D.N.Y.1993)(LMM).⁵

"The Second Circuit has made clear that '[a] plain reading of the language of Rule 26(c) demonstrates that the party seeking a protective order has the burden of showing that good cause exists for issuance of that order.... [I]f good cause is not shown, the discovery materials in question should not receive judicial protection and therefore would be open to the public for inspection. [W]e note that access [by class action litigants and the general public to discovery materials] is particularly appropriate when the subject matter of the litigation is of especial public interest." Gelb, 813 F.Supp. 1022, 1035, *citing* In re "Agent Orange", 821 F.2d 139, 145-46 (2d Cir.), *cert. denied*, 484 U.S. 926, 108 S.Ct. 289, 98 L.Ed.2d 249 (1987).

Courts in the Second Circuit have uniformly held that "The touchstone of the court's power under Rule 26(c) is the requirement of 'good cause.'" In re Parmalat Securities Litigation, 258 F.R.D. 236, 243 (S.D.N.Y. 2009) (LAK)(HBP), *citing* In re Zyprexa Injunction, 474 F.Supp.2d 385, 415 (E.D.N.Y.2007), *quoting* Seattle Times Co. v. Rhinehart, 467 U.S. 20, 36, 104 S.Ct. 2199, 81 L.Ed.2d 17 (1984). See also, Gelb, 813 F.Supp., 1036 ("As explained in John Does I-VI v. Yogi, 110 F.R.D. 629 (D.D.C.1986), "[t]o establish good cause under Rule 26(c) the courts have generally required a 'particular and specific demonstration of fact, as distinguished from stereotyped and conclusory statements.' ... With respect to the claim of confidential business information, this standard demands that the company prove that disclosure will result in a 'clearly defined and very serious injury to its business.'" *Id.* at 632 (quoting United States v. Exxon Corp., 94 F.R.D. 250, 251 (D.D.C. 1981) (citing United States v. IBM Corp., 67 F.R.D. 40, 46 (S.D.N.Y.1975))). Accord, Gratton v. United Parcel Service, Inc., 07-cv-3071 (E.D.N.Y. 2008) (TCP) (AKT). Debtors' Response does not qualify as a "particular and specific demonstration of fact", nor does it argue that disclosure will result in a "clearly defined and very serious injury to its business" and, as a consequence, it does not satisfy the good cause requirement.

The fact that business documents have been maintained as confidential does not automatically warrant continuation of that designation. See, e.g., Gelb, 813 F.Supp. 1035; see also Salomon Smith Barney, Inc. v. HBO & Co., 98 Civ. 8721(LAK), 2001 WL 225040 at *3 (S.D.N.Y. Mar. 7, 2001) ("Implicit in the notion of 'confidential business information' is something beyond the mere fact that the particular datum has not previously been made available to the public"). This

⁴ At the Deposition, Dr. Richard Fanelli testified that the research studies are not considered trade secrets; Fanelli Deposition 15:15-17:15

⁵ Upon direction of the Court, the NASAHC can produce the Documents, and the Fanelli transcript, or portions thereof.

decision cuts against Debtors' attempts to withhold consent to downgrading the Documents to 'public' status.⁶

To the extent that the Court retains jurisdiction and case management duties over these cases, Debtors' second argument that the Challenge Notices are moot lacks merit. See, Debtors' Response. There is also no justification for Debtors handcuffing release of the Documents to the formation, *in futuro*, of a repository in accordance with the timeline and terms envisioned under the Plan. *Id.* Further delay disadvantages and unduly prejudices all children suffering from fetal opioid exposure.

The Documents can be separated into the following categories as set forth in the accompanying Schedule: (A) Research Studies; (B) Fanelli Deposition exhibits; and (C) CCDS.

(A) The Research Studies reveal information that can prove beneficial and useful to NAS Claimants in connection with, for example, assessing and addressing long-term injuries due to fetal opioid exposure, especially for those babies that had been exposed to opioids in utero but such exposure did not ultimately result in a diagnosis of NAS, or signs of NOWS, at birth. The fact that much of the information contained in these Documents has not been revealed for one or more decades does not devalue its currency for NAS Claimants struggling with the long-term physical and cognitive manifestations due to fetal exposure to opioids. There is also no justification or need to continue to restrict access to this vital information to just those persons that have agreed to be bound by the PO. Continuation of confidentiality can only cause undue hardship and prejudice to NAS Claimants that have only filed a claim in due course but, for whatever reason (e.g., lack of knowledge, means or sophistication), never executed the PO. For the foregoing reasons, one or more of the Research Studies is not entitled to confidentiality.

(B) The Deposition Exhibits are not entitled to confidentiality. These documents span 1994-2010 and reveal significant knowledge, data and findings concerning pregnancy and risks of neonatal withdrawal, and of especial value to children exposed to opioids during this timeframe. The age of these communications undermine any need for continued confidentiality. Equally significant, none of these communications concern a pending application or contain trade secrets. Accordingly, immediate disclosure presents no undue risk of prejudice to Debtors, or risk of marketplace exploitation by competitors, or risk of an unfair benefit to any competitor.

(C) The CCDS materials are not entitled to confidentiality. The CCDS has been revised and updated numerous times since inception by Purdue, and it is believed that upwards of 20 versions of the CCDS are currently in existence, accessible, and maintained by Debtors, spanning as far back as 2000 (vol. 1). None of the information contained in the various versions of the CCDS is entitled to trade secret status, nor subject to improper competitive exploitation. However, entries in the CCDS relating to pregnancy reveal information [REDACTED]

⁶ *Schiller v. City of New York*, Nos. 04 Civ. 7922(KMK)(JCF), 04 Civ. 7921(KMK) (JCF), 2007 WL 136149 at *5 (S.D.N.Y. Jan. 19, 2007), *quoting In re Terrorist Attacks on Sept. 11, 2001*, 454 F.Supp.2d 220, 222 (S.D.N.Y.2006); *Blum v. Schlegel*, 150 F.R.D. 38, 41 (W.D.N.Y.1993) ("The party seeking protection from disclosure has the burden of making a particular and specific demonstration of fact, as distinguished from general, conclusory statements revealing some injustice, prejudice, or consequential harm that will result if protection is denied.").

related to in utero opioid exposure, a commonality of all NAS Claimants in this case. From the perspective of thousands of NAS Claimants, immediate and unfettered access to the information contained within the various CCDSs is beneficial to assessing injuries as well as for substantiating any related claims.

CONCLUSION:

For the foregoing reasons, the NSAHC respectfully requests that one or more of the Documents be downgraded to 'public' in all respects, as a matter of law and in the interests of justice.

Respectfully submitted,

CREADORE LAW FIRM PC

NAS Children Ad Hoc Committee Member

By: /s/ Donald E. Creadore

Donald E. Creadore, Esq.

TARTER KRINSKY & DROGIN LLP

Counsel for NAS Children Ad Hoc Committee

Scott S. Markowitz, Esq.

Rocco A. Cavaliere, Esq.

Michael Z. Brownstein, Esq.

1350 Broadway, 11th Floor

New York, NY 10018

Tel: (212) 216-8000

Scott S. Markowitz, Esq.

Rocco A. Cavaliere, Esq.

Michael Z. Brownstein, Esq.

Email: smarkowitz@tarterkrinsky.com

Email: rcavaliere@tarterkrinsky.com

Email: mbrownstein@tarterkrinsky.com

MARTZELL, BICKFORD & CENTOLA

Scott R. Bickford (LA 1165)

Spencer R. Doody (LA 27795)

338 Lafayette Street

New Orleans, LA 70130

Telephone: 504-581-9065

Facsimile: 504-581-7635

sbickford@mbfirm.com

srd@mbfirm.com

LAW OFFICES OF KENT HARRISON ROBBINS, P.A.

242 Northeast 27th Street

Miami, Florida 33137

Telephone: (305) 532-0500

Facsimile: (305) 531-0150

Email: KHR@khrlawoffices.com

REVISED SCHEDULE OF DOCUMENTS TO BE DOWNGRADED

*Add on Documents in Bold

SET 1:

i. Scientific Documents

1. PAK002329104-PAK002329635
2. PDD8013105299-PDD8013105304
3. PDD8013253884-PDD8013254903
4. PURCHI-000125871 – PURCHI-000128316 (previously cited as POK000386923-POK000389368)
5. PPLPC056000664380- PPLPC056000665191
6. PDD8013418569-PDD8013418582
7. PDD8013408689- PDD8013408698
8. E513 00045953- E513_00045962

ii. Fanelli Deposition Exhibits

1. PDD8002004532 -PDD8002004595
2. PKY-180604976 – PKY180605359
- 3. PMT003878825- PMT003878826, as part of PMT003878737 - PMT 003883905**
4. PPLPC0190000049101- PPLPC0190000049172

SET 2:

iii. Purdue's CCDS

- | | | |
|--------------------------|---------------------|----------|
| 1. Buprenorphine CCDS v1 | PPLPC013000078453 | 12/4/01 |
| 2. Buprenorphine CCDS v2 | PPLPC019000043760 | 1/28/04 |
| 3. Buprenorphine CCDS v3 | PPLPC001000028102 | 5/9/05 |
| 4. Buprenorphine CCDS v4 | PPLPC003000036627 | 4/1/10 |
| 5. Buprenorphine CCDS v5 | PPLPC019000838413 | 8/30/12 |
| 6. Buprenorphine CCDS v6 | PPLPC019001186411 | 12/11/14 |
| 7. Buprenorphine CCDS v7 | PPLPC018001298991 | 8/6/15 |
| 8. Buprenorphine CCDS v8 | PPLPC02000000994214 | 2/9/16 |
| 9. Hydromorphone CCDS v1 | PPLPC8856500091 | 1/30/01 |
| 10. Hydromorphone CCDSv2 | PPLPC001000220074 | 11/10/15 |
| 11. Hydromorphone CCDSv3 | PPLPC018001464512 | 8/24/17 |
| 12. Oxycodone CCDS v1 | PLPC013000063753 | 12/14/00 |
| 13. Oxycodone CCDS v2 | PPLPC037000025825 | 4/24/02 |
| 14. Oxycodone CCDS v3 | PPLPC037000035237 | 10/10/03 |
| 15. Oxycodone CCDS v5 | PPLPC037000049710 | 4/8/04 |
| 16. Oxycodone CCDS v6 | PPLPC018001145603 | 6/27/06 |
| 17. Oxycodone CCDS v7 | PPLPC018000340916 | 11/29/07 |
| 18. Oxycodone CCDS v8 | PPLPC007000009307 | 8/7/09 |
| 19. Oxycodone CCDS v9 | PPLPC006000000231 | 8/12/11 |
| 20. Oxycodone CCDS v9.1 | PPLPC001000093447 | 8/29/11 |
| 21. Oxycodone CCDS v9.2 | PPLPC018000782644 | 1/30/13 |

22. Oxycodone CCDS v10	PPLPC001000146900	2/22/13
23. Oxycodone CCDS v11	PPLPC018000978892	5/21/14
24. Oxycodone CCDS v12	PPLPC002000227143	10/30/15
25. Oxycodone CCDS v13	PPLPC019001389363	4/5/17

Additional CCDS

26. Buprenorphine CCDSv.5.1	PPLPC030000802402	10/3/13
27. Oxycodone CCDS v4	PPLPC037000038602	11/24/03
28.Oxycodone 2011 Draft	PPLPC019000764982	12/2/11

EXHIBIT A

From: donald@creadorelawfirm.com <donald@creadorelawfirm.com>

Sent: Thu, Nov 18, 2021 at 2:50 pm

To: McClammy, James I.

Cc: Knudson, Jacquelyn Swanner, Townes, Esther C., Hoff, Robert, Kent Harrison Robbins - KHR Law Offices, Kevin Thompson, Scott R. Bickford, Hayden.Coleman@dechert.com, donald@creadorelawfirm.com

BANKRUPTCY- PURDUE-NASAHC-NTP-requests-fanelli-pkt-11-18-2021.pdf (27.8 KB)

BANKRUPTCY- PURDUE-2004-NASAHC-MOTION2REFILE-11-18-2021.pdf (9.5 MB) — Download all

Hello Jim-

1.

Attached please find a courtesy version of the materials being filed into the docket.

2.

Also attached as a separate pdf file is a set of materials with relevant bates numbers. Included in this list are certain (but not all) of the documents introduced as exhibits at the Dr. Fanelli deposition. As a general matter we contend that downgrading each of these documents (to public) will not cause any competitor to acquire a competitive advantage; additionally, for the reasons set forth in the 2-page grid attached, downgrading of these materials to 'public' will benefit the ongoing efforts of the Trust Administrator and others, such as NAS experts and other professionals.

For avoidance of any doubt, this communication constitutes a Challenge Notice in conformity with the terms and conditions outlined in the prevailing protective order. The NASAHC is notifying Debtors that the NASAHC has a good faith belief to assert that the designations attached to the identified documents were not proper and, as a consequence, removal of the confidentiality designations that presently apply to each of these documents is proper and justified.

We look forward to your responses and courtesies.

We are happy to discuss.

Many thanks,

Don

o/b/o NAS Children Ad Hoc

-----Original Message-----

From: "McClammy, James I." <james.mcclammy@davispolk.com>

Sent: Wednesday, November 10, 2021 1:02pm

To: "donald@creadorelawfirm.com" <donald@creadorelawfirm.com>

Cc: "Knudson, Jacquelyn Swanner" <jacquelyn.swanner@davispolk.com>, "Townes, Esther C."

<esther.townes@davispolk.com>, "Hoff, Robert" <RHoff@wiggin.com>, "Kent Harrison Robbins - KHR Law Offices" <khrlawoffices.com>, "Kevin Thompson" <kwthompsonwv@thompsonbarneylaw.com>, "Scott R. Bickford" <srb@mbfirm.com>, "Hayden.Coleman@dechert.com" <Hayden.Coleman@dechert.com>

Subject: Re: 19-CV-23649 (RDD)

Would folks be available for a call on Friday at 1:00 pm to discuss the below?

J.I.M.

On Nov 9, 2021, at 11:49 AM, donald@creadorelawfirm.com wrote:

Hello Jim-

We want to circle back on some outstanding matters, including:

1. advising Debtors of the imminent filing of motion to refile (documents as public);
2. status and protocol of Fanelli deposition; have debtors forwarded the original with errata sheet to Fanelli or, alternatively, should we send to DPW, or to Wiggins, for forwarding?

Purdue De-Designation of Discovery Documents for [REDACTED]

Document	Reason for De-Designation	Bates
[REDACTED] Study in Rats [REDACTED]	[REDACTED]	[REDACTED] [REDACTED]
[REDACTED] toxicity study in rats [REDACTED]	[REDACTED]	[REDACTED] PDD8013105304 (only a summary document was located)
[REDACTED] Study in Rats	[REDACTED]	PDD8013253884- PDD8013254903
[REDACTED] Development Study [REDACTED] in Rats	[REDACTED]	POK000386923- POK000389368
2016 Periodic Safety Update Report for Oxycodone	[REDACTED]	PPLPC056000664380
Periodic Safety Update Report 2006-2007	[REDACTED]	PDD8013418569- PDD8013418582
Periodic Safety Update	[REDACTED]	PDD8013408689-

Privileged & Confidential Attorney Work Product of NAS Ad Hoc Committee

Report 2007-2008	[REDACTED]	PDD8013408698
1994 ANDA Oxycodone	[REDACTED]	PDD8002004532; Fanelli Exhibit 4
1997 Oxycodone ANDA	[REDACTED]	PKY180604976; Fanelli Exhibit 6
Redesigning Purdue R&D For Long Term Success 2004 presentation	[REDACTED]	PPLPC019000004910; Fanelli Exhibit 8
Adverse Event Reports Jan 1990 - Oct 2018	[REDACTED]	PPLP004390587; Fanelli Ex. 11
2010-2011 Oxycodone PSUR	[REDACTED]	PMT003878225; Fanelli Ex. 12
Swedish SMPC Opidol Summary of Product Characteristics draft	[REDACTED]	E513_00045953
Swedish SMPC Opidol Summary of Product Characteristics draft II	[REDACTED]	E513_00046100

19-cv-23649 (RDD)

From: donald@creadorelawfirm.com <donald@creadorelawfirm.com>

Sent: Mon, Nov 22, 2021 at 2:35 pm

To: McClammy, James I., Knudson, Jacquelyn Swanner, Townes, Esther C., Hoff, Robert, Kent Harrison Robbins - KHR Law Offices, Kevin Thompson, Scott R. Bickford, Hayden.Coleman@dechert.com

Cc: donald@creadorelawfirm.com

Opioid-CCDS-timelines FOR NEW REQUESTS 11-18-21 wk (1).pdf (90.9 KB)

Jim-

As Debtors requested, and in furtherance of our communications relating to Purdue's CCDS, for greater specificity attached please find a one-page list of bates references (here, reference to the beginning Bates encompasses the Bates range of the document as defined by the producing party) and other identifiers to the versions of the CCDS that the NASAHC seeks to have downgraded to public. On the basis that downgrading each of these documents (to public) will not cause any competitor to acquire a competitive advantage, we are seeking the consent of Debtors in accordance with the protocol set forth in the protective order.

For avoidance of any doubt, this communication constitutes a Challenge Notice in conformity with the terms and conditions outlined in the prevailing protective order. The NASAHC is notifying Debtors that the NASAHC has a good faith belief to assert that the designations attached to the identified documents were not proper and, as a consequence, removal of the confidentiality designations that presently apply to each of these documents is proper and justified.

We are happy to discuss and are available for a meet and confer this week.

Many thanks,

Don

o/b/o NAS Children Ad Hoc

Donald E. Creadore

The Creadore Law Firm, P.C.

450 Seventh Avenue - Suite 1408

New York, New York 10123

(O) 212.355.7200

(C) 917.226.1881

donald@creadorelawfirm.com

CONFIDENTIALITY NOTICE: The information contained in this email message is protected under the Electronic Communications Privacy Act, 18 U.S.C. 2310-2321, and may also be protected by attorney-client and/or the attorney/work product privileges. It is intended only for the use of the individual named above and the privileges are not waived by virtue of this having been sent by email. If the person actually receiving this email or any other reader of the email is not the named recipient, any use, dissemination, distribution, or copying of the communication is strictly prohibited. If you have received this communication in error, please immediately notify us by telephone at 212-355-7200 and return the original message to us.

SPECIAL NOTICE TO CLIENT(S): If you are a client of this firm and this e-mail is directed to you. DO NOT FORWARD to any other party, or you could be waiving the attorney-client privilege.

Doc	Bates #	Dated
Buprenorphine CCDS v1	PPLPC013000078453	12/4/01
Buprenorphine CCDS v2	PPLPC019000043760	1/28/04
Buprenorphine CCDS v3	PPLPC001000028102	5/9/05
Buprenorphine CCDS v4	PPLPC003000036627	4/1/10
Buprenorphine CCDS v5	PPLPC019000838413	8/30/12
Buprenorphine CCDS v6	PPLPC019001186411	12/11/14
Buprenorphine CCDS v7	PPLPC0 18001298991	8/6/15
Buprenorphine CCDS v8	PPLPC02000000994214	2/9/16
Hydromorphone CCDS v1	8856500091	1/30/01
Hydromorphone CCDS v2	PPLPC001000220074	11/10/15
Hydromorphone CCDS v3	PPLPC018001464512	8/24/17
Oxycodone CCDS v1	PPLPC013000063753	12/14/00
Oxycodone CCDS v2	PPLPC037000025825	4/24/02
Oxycodone CCDS v3	PPLPC037000035237	10/10/03
Oxycodone CCDS v4	PPLPC037000035237	11/24/03
Oxycodone CCDS v5	PPLPC037000049710	4/8/04
Oxycodone CCDS v6	PPLPC018001145603	6/27/06
Oxycodone CCDS v7	PPLPC018000340916	11/29/07
Oxycodone CCDS v8	PPLPC007000009307	8/7/09
Oxycodone CCDS v9	PPLPC006000000231	8/12/11
Oxycodone CCDS v9.1	PPLPC001000093447	8/29/11
Oxycodone CCDS v9.2	PPLPC018000782644	1/30/13
Oxycodone CCDS v10	PPLPC001000146900	2/22/13
Oxycodone CCDS v11	PPLPC018000978892	5/21/14
Oxycodone CCDS v12	PPLPC002000227143	10/30/15
Oxycodone CCDS v13	PPLPC019001389363	4/5/17

EXHIBIT B

From: Knudson, Jacquelyn Swanner <jacquelyn.swanner@davispolk.com>
Sent: Tue, Nov 23, 2021 at 7:42 pm
To: donald@creadorelawfirm.com, McClammy, James I.
Cc: Townes, Esther C., Hoff, Robert, Kent Harrison Robbins - KHR Law Offices, Kevin Thompson, Scott R. Bickford, Hayden.Coleman@dechert.com

2021.11.23_J. McClammy Ltr. to NAS Committee re Challenge Notice.PDF (127.8 KB)

Don—

Please find attached a letter from Jim in response to your challenge notices sent via email on Thursday, November 18, 2021, and Monday, November 22, 2021. If you think it would be helpful to discuss, we can be available for a call next Wednesday, December 1.

Best,
Jacquelyn

Jacquelyn Swanner Knudson

+1 212 450 3341 office
+1 803 417 3273 mobile
jacquelyn.swanner@davispolk.com

Davis Polk & Wardwell LLP

Confidentiality Note: This email is intended only for the person or entity to which it is addressed and may contain information that is privileged, confidential or otherwise protected from disclosure. Unauthorized use, dissemination, distribution or copying of this email or the information herein or taking any action in reliance on the contents of this email or the information herein, by anyone other than the intended recipient, or an employee or agent responsible for delivering the message to the intended recipient, is strictly prohibited. If you have received this email in error, please notify the sender immediately and destroy the original message, any attachments thereto and all copies. Please refer to the firm's [Privacy Notice](#) for important information on how we process personal data. Our website is at davispolk.com.

From: donald@creadorelawfirm.com <donald@creadorelawfirm.com>
Sent: Thursday, November 18, 2021 2:51 PM
To: McClammy, James I. <james.mcclammy@davispolk.com>
Cc: Knudson, Jacquelyn Swanner <jacquelyn.swanner@davispolk.com>; Townes, Esther C. <esther.townes@davispolk.com>; Hoff, Robert <rhoff@wiggins.com>; Kent Harrison Robbins - KHR Law Offices <KHR@khrlawoffices.com>; Kevin Thompson <kwthompsonwv@thompsonbarneylaw.com>; Scott R. Bickford <srb@mbfirm.com>; Hayden.Coleman@dechert.com; donald@creadorelawfirm.com
Subject: Re: 19-CV-23649 (RDD)

Hello Jim—

1.
Attached please find a courtesy version of the materials being filed into the docket.

2.
Also attached as a separate pdf file is a set of materials with relevant bates numbers. Included in this list are certain (but not all) of the documents introduced as exhibits at the Dr. Fanelli deposition. As a general matter we contend that downgrading each of these documents (to public) will not cause any competitor to acquire a competitive advantage; additionally, for the reasons set forth in the 2-page grid attached, downgrading of these materials to 'public' will benefit the ongoing efforts of the Trust Administrator and others, such as NAS experts and other professionals.

For avoidance of any doubt, this communication constitutes a Challenge Notice in conformity with the terms and conditions outlined in the prevailing protective order. The NASAHC is notifying Debtors that the NASAHC has a good faith belief to assert that the designations attached to the identified documents were not proper and, as a consequence, removal of the confidentiality designations that presently apply to each of these documents is proper and justified.

We look forward to your responses and courtesies.
We are happy to discuss.
Many thanks,

Davis PolkJames I. McClammy
+1 212 450 4584
james.mcclammy@davispolk.comDavis Polk & Wardwell LLP
450 Lexington Avenue
New York, NY 10017
davispolk.com

November 23, 2021

Re: Ad Hoc Committee of NAS Children Challenge Notices Dated November 18, 2021, and November 22, 2021, *In re Purdue Pharma L.P.*, No. 19-23649 (RDD) (Bankr. S.D.N.Y.)

Dear Don:

This letter constitutes the Debtors' written response to your challenge notices under the terms of the *Third Amended Protective Order* [Dkt. No. 1935] (the "**Protective Order**") sent via email on Thursday, November 18, 2021, and Monday, November 22, 2021 (together, the "**Challenge Notices**"). With the exception of the "Swedish SMPC Opidol Summary of Product Characteristics Draft II," which the Debtors have already agreed to make public,¹ the Debtors do not agree to making the remaining documents referenced in the Challenge Notices public by filing them on the bankruptcy docket for the following reasons, among others.

First, the issue of which documents to make public and when such documents will be made public is already firmly established under the Debtors' twelfth amended plan of reorganization [Dkt. No. 3726] (the "**Plan**"), which provides for the largest public document repository in history with a budget of \$44 million. (See Plan § 5.12.) The terms and conditions of the public document repository were the subject of intense negotiations before a mediator, and by voting overwhelmingly to approve the Plan, these terms and conditions were accepted by the creditors, including the NAS Committee.

Moreover, the majority of the documents that you request be downgraded to "public," including but not limited to the Adverse Event Report, Periodic Safety Update Reports, and FDA applications, will require a page-by-page review to apply redactions for personally identifying information before the documents can be made public. With over 19,000 pages that would need to be reviewed for potential redactions, now is not the appropriate time to undertake such a timely and costly review, *especially* since, as just discussed, the Plan explicitly addresses this very issue. The Bankruptcy Court for the Southern District of New York (the "**Court**") has approved the Plan [Dkt. No. 3787], the members of the Document Oversight Board have been selected, and the process of selecting and processing documents for inclusion in the public document repository will begin as soon as the Plan goes effective. In light of the foregoing, and given the hugely expensive endeavor associated with these requests (and additional piecemeal requests likely to be forthcoming), the Debtors, as fiduciaries of the estates, cannot and will not make any costly and time-consuming side deals with individual creditor groups that circumvent the process established under the Plan for reviewing, redacting, and releasing the Debtors' documents.

Second, your request is moot. The sole purpose of discovery in these cases—and in fact, in all civil cases—is to assist parties in the case with resolving a particular dispute currently before the court. See *Haidon v. Town of Bloomfield*, 2021 WL 3124205, at *4-5 (D. Conn. 2021); *In re Zyrpexa Injunction*, 474 F. Supp. 2d 385, 414 (E.D.N.Y. 2007). All documents subject to the Protective Order, including the documents listed in the Challenge Notices, were produced for use in connection with resolving the chapter 11 cases before the Court. Given that the Court has confirmed the Debtors' Plan and that these documents

¹ See Stipulation and Agreed Order Regarding Unsealing of Certain Materials Filed in Connection with the NAS Children Ad Hoc Committee's Rule 2004 Motion and Reply (Oct. 15, 2021), Dkt. No. 3960.

DavisPolk

were not designated as part of the record of the appeal currently pending before the district court,² there is no dispute before the Court that would require the filing of these documents on the bankruptcy docket. As a result, the confidentiality designations are not limiting the NAS Committee's participation in these cases in any way.

Third, the documents subject to the Challenge Notices are correctly designated as either "Confidential Information"³ or "Highly Confidential Information"⁴ under the Protective Order. The documents designated as "Confidential" contain personally identifying information and/or research and technical information that the Debtors have maintained as confidential. The four remaining documents designated as "Highly Confidential" contain information that, if made public, would allow market participants to gain an unfair advantage. Accordingly, these documents fit squarely within the definitions set forth in the Protective Order and are entitled to protection.

Best regards,

/s/ James I. McClammy

James I. McClammy

Electronic Delivery

² See Ex. A, Omnibus Designation & Counter-Designation of Appellate Record, *In re Purdue Pharma L.P., et al.*, *Bankruptcy Appeals*, No. 21-cv-7532 (CM) (Lead Case) (S.D.N.Y. Oct. 21, 2021), Dkt. No. 78.

³ Under the Protective Order, "'Confidential Information' means any Discovery Material designated as Confidential on the basis that it constitutes, reflects, discloses, or contains information that is or could be protected from disclosure by law as (i) personally identifying information, (ii) personal information relating to a Family Member, (iii) medical or psychiatric information, (iv) personnel records, (v) law enforcement materials, (vi) research, technical, commercial, financial, banking, or investment information that the Producing Party has maintained as confidential, (vii) such other proprietary or sensitive business or commercial information that is not publicly available, or (viii) other such information that would be entitled to protection on a motion for a protective order pursuant to Federal Rule of Civil Procedure 26(c), as incorporated by Federal Rule of Bankruptcy Procedure 7026." (Protective Order ¶ 8.)

⁴ Under the Protective Order, "'Highly Confidential Information' means any Discovery Material designated as Highly Confidential that constitutes, reflects, discloses, or contains information the Producing Party has maintained as confidential and (i) the disclosure of which would allow a Market Participant to gain a material advantage in the marketplace such that it qualifies as a trade secret under applicable law, or (ii) the disclosure of which would be likely to cause commercial harm to the Producing Party or to the business partners or counterparties of the Producing Party." (Protective Order ¶ 15.)

DEBTORS' RESPONSE TO CHALLENGE LETTER

EXHIBIT B

December 14, 2021

Re: In re Purdue Pharma L.P., et al., No. 19-23649 (RDD) NAS Children Ad Hoc Committee Challenge Letter

Hon. Robert D. Drain
U.S. Bankruptcy Court for the Southern District of New York
300 Quarropas Street
White Plains, NY 10601

Dear Judge Drain:

We write on behalf of Purdue Pharma L.P. and its affiliated debtors and debtors in possession in the above-captioned matter (collectively, the “**Debtors**”) in response to the NAS Children Ad Hoc Committee’s (the “**NASC**”) December 9, 2021 letter (the “**Challenge Letter**”) regarding downgrading to “public” certain of the Debtors’ confidential or highly-confidential business, research, and development documents (the “**Challenged Documents**”). The Challenge Letter should be denied because (i) as a result of negotiations involving the NASC, the Debtors’ twelfth amended plan [Dkt. No. 3726] (the “**Plan**”)¹ provides for an organized process to review, redact, and release documents like those identified in the Challenge Letter, (ii) the NASC’s stated reasons for the request do not warrant public dissemination of the Challenged Documents now, and (iii) good cause exists to maintain the Challenged Documents’ confidentiality designations.

I. Public Disclosure of the Debtors’ Documents is Governed by the Plan

The NASC’s Challenge Letter attempts to circumvent the agreement among key parties in these cases regarding when and how certain of the Debtors’ non-public documents will be disclosed to the public. The NASC’s assertion that “[t]here is no justification for [the] Debtors handcuffing release of the [Challenged] Documents to the formation . . . of a repository . . . under the Plan” (Challenge Ltr. at 5), cannot be reconciled with, and, indeed, is readily contradicted by, the record of these cases, including the Plan and the NASC’s own representations about the “hard fought” agreement by the parties regarding the contours of the public document repository. See Nov. 30, 2021 Hr’g Tr. 202:20-205:25, *In re Purdue Pharma Bankruptcy Appeals*, No. 21 Civ. 7532(CM), *et seq.*, Dkt. No. 273 (noting that the creation and funding of the repository was a “very, very hard

¹ Capitalized terms used but not defined herein shall have the meaning ascribed to them in the Plan.

fought issue” in the cases and characterizing the documents to be included in the public document repository as “valuable consideration” under the Plan).

Pursuant to the carefully-negotiated provisions of the Plan, “[o]n the Effective Date, or as soon as reasonably practicable thereafter, the [disclosure oversight board (“**DOB**”)] shall be provided access to a set of non-privileged materials for the purpose of accomplishing the Public Document Repository,” including documents obtained during the [c]hapter 11 [c]ases by the NAS[C] regarding clinical and pre-clinical studies conducted by the Debtors or other companies associated with the Sackler Family Members.” (Plan § 5.12(f)(v) (emphasis added).) Notably, part of the responsibilities of the DOB will be “directing the use of the [d]isclosure [p]rogram [b]udget” to fund “the disclosure program designed to avoid unnecessary expense” including “by using negotiated agreements to avoid the need for litigation.” (*Id.* § 5.12(e), (l)(iii)). Moreover, the DOB will be responsible for “establishing procedures for [p]rotected information” and “for resolution of challenges to the redaction or disclosure of information.” (*Id.* § 5.12(l)(iv)-(v).) The NASC should not be allowed to undermine that bargained-for process by seeking public disclosure of those same documents now, before the Plan’s Effective Date. This is especially true when there is no live issue pending before this Court to which these documents relate.

II. The Stated Reasons for the Need for Public Dissemination of the Challenged Documents Are Ill-Founded

The NASC’s purported needs for immediate public disclosure of the Debtors’ confidential documents are neither credible nor warranted under the Federal Rules of Civil Procedure.

First, the NASC argues that the need for public access to the Challenged Documents is “immediate, real[,] and credible” in order to “afford immediate relief to all children that suffer from fetal opioid exposure by, for instance, assisting them in assessing injuries and, also, enhancing their understanding of fetal opioid exposure and the need for treatment of children injured by fetal opioid exposure.” (Challenge Ltr. at 1-2.) While laudable, this purported reason highlights the inappropriateness of the NASC’s request. The purpose of discovery is not to generally educate the public. It is true that the Federal Rules of Civil Procedure allow for broad discovery, but the Supreme Court has made clear that “[l]iberal discovery is provided for the sole purpose of assisting in the preparation and trial, or the settlement, of litigated disputes.” *Seattle Times Co. v. Rhinehart*, 467 U.S. 20, 34 (1984) (emphasis added); *see also In re Zyprexa*, 474 F. Supp. 2d 385, 415 (E.D.N.Y. 2007), *aff’d sub nom. Eli Lilly & Co. v. Gottstein*, 617 F.3d 186 (2d Cir. 2010) (noting that the “overarching purpose of the discovery process” is to “facilitate orderly preparation for trial, not to educate or titillate the public” (quoting *Joy v. North*, 692 F.2d 880, 893 (2d Cir. 1982))). “Put simply, the Federal Rules’ broad discovery regime is meant to assist parties in resolving a particular case”—a purpose that “has almost nothing to do with the public.” *Haidon v. Town of Bloomfield*, 2021 WL

3124205, at *4-5 (D. Conn. 2021) (emphasis added). This Court confirmed the Debtors' Plan on September 17, 2021 [Dkt. No. 3787], the NASC has no motion pending before this Court, and the Challenged Documents were not designated as part of the record of the appeal currently pending before the district court.² Accordingly, there is no case or active dispute before any court in connection with these cases that would require that the Challenged Documents be made available to the public now. Against this backdrop, the NASC's discovery request clearly demonstrates why such requests should be handled at the appropriate time via the process for the public document repository that the parties spent considerable time, effort, and resources negotiating.

Second, the NASC asserts that public access to the Challenged Documents is necessary because they "contain information that is relevant, material[,] and beneficial to NAS Claimants in terms of . . . assessing injuries like congenital malformations, heart defects, brain damage[,] and other long-term impacts." (Challenge Ltr. at 1-2.) The NASC further asserts that "[t]he findings and entries reported in these scientific documents are among the reference sources the NAS[C] relied upon for establishing the list of medical conditions qualifying under the NAS PI TDP." (*Id.* at 2.) This makes no sense as a basis for public disclosure. Claimants entitled to distributions under the NAS PI TDP already must have filed proofs of claims in these cases against the Debtors for compensation related to their NAS-related injuries. In other words, even crediting the NASC's assertion that the decades-old rat studies specifically aided its contributions to developing qualifying medical conditions under the NAS PI TDP, the NASC offers no reason how or why rat studies would assist an NAS claimant in determining whether they currently have or have had a document from a licensed medical provider or other medical records evidencing "injuries like congenital malformations, heart defects, brain damage[,] and other long-term impacts" related to opioid exposure or use, which is what is required under the NAS PI TDP. (NAS PI TDP § 4, JX-1607.)

III. Good Cause Exists to Maintain the Confidentiality Designations

All of the Challenged Documents are "documents produced by the parties in discovery" and are not judicial documents. See *In re Zyprexa*, 474 F. Supp. 2d at 412. Accordingly, the Debtors "need only make a baseline showing of good cause in order to justify the imposition of a protective order." *Sharpe v. Cnty. Of Nassau*, 2016 WL 7350690, at *4 (E.D.N.Y. 2016) (citations omitted). To determine whether "good cause" exists, courts balance "the need for information against the injury that might result if uncontrolled disclosure is compelled." *In re Zyprexa*, 474 F. Supp. 2d at 415.³

² See Ex. A, Omnibus Designation & Counter-Designation of Appellate Record, *In re Purdue Pharma L.P., et al.*, Bankruptcy Appeals, No. 21-cv-7532 (CM) (Lead Case) (S.D.N.Y. Oct. 21, 2021), Dkt. No. 78.

³ Contrary to the NASC's suggestion (Challenge Ltr. at 4), there is no established "particular and specific demonstration of fact" requirement. See *Schoolcraft v. Cty. of New York*, 2013 WL 4534913, at *3 & n.3.

The Challenged Documents include: (i) scientific studies submitted to the FDA, (ii) periodic safety update reports (“**PSURs**”) submitted to the FDA, (iii) a research and development (“**R&D**”) presentation, and (iv) company core data sheets (“**CCDSs**”). The majority of the documents fit squarely within categories (vi) and (vii) of the definition of “Confidential Information”⁴—the lowest level of confidentiality under the Protective Order.⁵ The Challenged Documents contain research and technical information that the Debtors have maintained as confidential in the ordinary course of business as a pharmaceutical company and/or sensitive business and commercial information that is not publicly available. The scientific studies—which contrary to the NASC’s “information and belief” (Challenge Ltr. at 2), were submitted to the FDA as part of the OxyContin new drug application but not made publicly available—are at the core of its business and strategic decision-making. The Debtors invested significantly to develop or acquire this type of R&D information, which is critical to the stability, success, and competitiveness of the Debtors until emergence and, more importantly, the reorganized entity Knoa Pharma (“**Knoa**”). Release of this information could harm the Debtors and Knoa by giving competitors an unfair advantage. See, e.g., *Pub. Citizen Health Research Grp. v. Food & Drug Admin.*, 185 F.3d 898, 905 (D.C. Cir. 1999) (holding that disclosure of R&D data submitted in connection with a new drug application to the FDA “would cause substantial harm to [the drug maker’s] competitive position”); *Verde Env’t Techs., Inc. v. C2R Glob. Mfg. (In re C2R Glob. Mfg.)*, No. 18-30182-BEH, 2020 WL 7265867, at *3 (Bankr. E.D. Wis. Dec. 10, 2020) (sealing R&D information because it contained “confidential information regarding the design, development, and testing” of the debtor’s product). The same is true of the PSURs and CCDSs, which contain or discuss scientific studies, clinical trials, or adverse events, and are replete with confidential data and analyses. The R&D presentation is a sensitive, internal business document that discusses strategies for

(S.D.N.Y. 2013) (quotations and citations omitted) (noting intra- and inter-circuit split). Indeed, certain courts in the Second Circuit have “dispensed with the specificity requirement, only demanding that the moving part show good cause.” *Id.* Notably, although the Second Circuit has not yet decided the issue, “it has issued several opinions that cite to Rule 26(c)’s good cause requirement without noting an attendant specificity requirement.” *Id.*

⁴ Under the Protective Order, “‘Confidential Information’ means any Discovery Material designated as Confidential on the basis that it constitutes, reflects, discloses, or contains information that is or could be protected from disclosure by law as . . . (vi) research, technical, commercial, financial, banking, or investment information that the Producing Party has maintained as confidential, [or] (vii) such other proprietary or sensitive business or commercial information that is not publicly available” (Protective Order ¶ 8.)

⁵ Four documents contain “Highly Confidential” designations from prior litigations. Pursuant to the Protective Order, and as agreed by the parties to expedite and reduce the cost of discovery, these documents were reproduced in these cases with the “‘Highly Confidential’ designation from other litigations . . . without any need to re-designate” the documents. (Protective Order ¶ 15.) In light of the fact that the Protective Order was carefully negotiated, and these documents will be eligible to be part of the public document repository discussed in Section I, the current confidentiality designations should be maintained.

improving the Debtors' R&D.⁶ Release of this information could provide competitors with direct insight into how the Debtors manage, budget, and execute R&D projects in the United States and abroad.⁷

Finally, good cause also exists to maintain the Challenged Documents' designations until the appropriate time in order to avoid opening the floodgates to additional, similar, premature requests (from the NASC or otherwise) for dissemination of incomplete, internal documents that could be taken out of context, particularly given the pending appeal, at the expense of the Debtors' estates. See, e.g., *In re Zyprexa*, 474 F. Supp. 2d at 415 (issuing an injunction to prevent dissemination of documents where disclosure created the probability of prejudice largely irrelevant to the issues posed by the pending cases); *Gelb v. Am. Tel. & Tel. Co.*, 813 F. Supp. 1022, 1035 (S.D.N.Y. 1993) (noting that "the possibility of commercially damaging exploitation of . . . internal documents prior to trial [was] a consideration th[e] [c]ourt c[ould] not ignore" even where "[t]he interest in disclosure [was] . . . very high in th[e] case").⁸ Balancing this potential harm against the NASC's lack of any logical need for the information now when the Debtors' public document repository will be established in due course (see *supra* Sections I & II), counsels in favor of maintaining the confidentiality designations. Indeed, as the Debtors seek to maintain only the "modest protective order limiting the use of [the Challenged Documents] to litigation of the instant case," the "low hurdle" to meet Rule 26(c)'s good cause standard is satisfied. See *Haidon*, 2021 WL 3124205, at *7. Accordingly, the request that the Challenged Documents be downgraded to public should be overruled and the confidentiality designations of the Challenged Documents maintained.

⁶ The age of a document, in itself, does not remove documents from the scope of confidential protection (see Challenge Ltr. at 4-5), particularly where, as here, valid reasons exist to maintain protection of the documents from general public dissemination. See, e.g., *Grand River Enters. Six Nations, Ltd. v. King*, No. 02 Civ. 5068(JFK), 2009 WL 222160, at *3-4 (S.D.N.Y. Jan 30, 2009) (noting that 10-year-old commercial information could still be sensitive, where business plans identified trends and strategies that could be "extrapolated out to the present day and show how [a party] intends to compete").

⁷ To clarify, there is no "Central Repository, Stamford CT" as that term has been used by the NASC. (Challenge Ltr. at 2, n. 1.) Indeed, Dr. Fanelli testified that (a) the "central repository" was not a term he remembered using but was only seen as a footnote or reference in some early documents, like the OxyContin NDA; and (b) it refers to a "the regulatory document base, which was either that room or now an electronic database" (Deposition of R. Fanelli, 166:3-14 (Oct. 12, 2021)—the same electronic copies of regulatory documents that the Debtors have already spent considerable time and resources searching in response to the NASC's requests. (Decl. of James I. McClammy ¶¶ 18-20 (April 1, 2021), Dkt. No. 2585.)

⁸ See also *Margiotta v. City of Gloversville*, No. 607CV0560DNHGH, 2008 WL 11505863, at *2 (N.D.N.Y. Aug. 11, 2008) (explaining that the cited portion of *Agent Orange* articulating an "especial public interest" and statutory right of access to discovery materials by virtue of Rule 5(d) is "no longer good law") (citation omitted).

DavisPolk

Hon. Robert D. Drain

Respectfully submitted,

/s/ James I. McClammy

James I. McClammy

Electronic Delivery